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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/810,412

Applicant(s)

ASANO ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 3-20, 22, 24-29, 32, 34-36, 38 is/are rejected.
- 7) ☒ Claim(s) 21, 23, 30, 31, 33 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Applicant's arguments filed 14 June 2007 have been fully considered but they are not persuasive.

Applicant has argued that Conn (US Patent 6438414) does not anticipate the claimed invention because it does not teach the claimed electrode contact areas with sufficient specificity – that is, Applicant feels that Conn's contact area range of 30 to 100 mm² does not anticipate the claimed range of .01 to 50 mm². Conn overlaps 40% of the claimed range; though Conn's preferred contact area is outside the claimed range, Conn clearly considers all values within the range to be appropriate for use. Applicant has stated that a contact area of less than 50 mm² provides unexpected results, but has not provided any evidence to support this allegation. As such, the Examiner feels that Conn does provide sufficient specificity to anticipate the present claims.

Regarding Applicant's argument that Conn does not disclose forming analyte transmission paths prior to application of the electrode, Conn also discloses techniques for enhancing transmission, such as pricking with microneedles, which would inherently form transmission paths before the electrodes are applied.

Regarding Applicant's argument that the range in Kim (US Patent 6736777) of 10 to 300 mm² does not have sufficient specificity to anticipate the claimed range of 0.01 to 50 mm², Examiner must point out that Kim overlaps 80% of the claimed range. Again, though Kim's preferred area is greater than the claimed range, Applicant has not provided evidence of unexpected results that would render the overlapping range moot.

Claim Rejections - 35 USC § 102

3. Claims 1, 4-7, 13, 15, 17-18, 24-25, 28-29, and 36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Conn.

Regarding Claim 1, Conn discloses a device comprising a first electrode part (elements 4, 8 and 12) having a contact area of between about 0.01-50 mm² (column 18, lines 4-6); a second electrode part (element 14); and a component to supply power to the first and second electrodes in order to extract an analyte (column 15, lines 24-36).

Regarding Claim 4, Conn further discloses that the power supply part supplies a current of less than about 300 uA (column 15, lines 38-39).

Regarding Claim 5, Conn further discloses that the first electrode part comprises an electrode connected to the power source (element 14), and a collection material (elements 4 and 8) that is connected to the electrode (column 15, lines 29-36).

Regarding Claim 6, Conn further discloses that the collection material is in contact with the patient's skin (column 3, lines 54-59).

Regarding Claim 7, Conn further discloses that the electrode part is detachable from the power supply part (column 15, lines 24-25), since a non-rechargeable battery must be removed (detached) in order to allow replacement.

Regarding Claim 13, Conn further discloses that the power supply part may be a constant-voltage power supply (column 15, lines 24-25), because a battery supplies constant voltage.

Regarding Claim 15, Conn further discloses that the device may comprise a part for accelerating or promoting analyte extraction (column 8, line 64 - column 9, line 7).

Regarding Claim 17, Conn further discloses that the analyte is glucose (column 16, lines 39-43).

Regarding Claim 18, Conn further discloses that the overall system comprises an assay part for assaying the analyte extracted in the first electrode part and for outputting a signal corresponding to the analyte's concentration (column 16, lines 31-38); an analysis part for analyzing the concentration signal (column 18, lines 42-50); and an output part for outputting the analysis result (column 18, lines 47-48).

Regarding Claim 24, Conn discloses a method comprising placing two electrode parts on skin, one of which has a contact area of between about 0.01-50 mm² (column 15, lines 24-34; column 18, lines 4-6); applying electrical energy to the electrode parts (column 15, lines 27-34); and extracting analyte at the first electrode part (column 15, lines 34-36).

Regarding Claim 25, Conn further discloses that the contact area may be about 25 mm² (column 18, lines 4-6).

Regarding Claim 28, Conn further discloses that the method comprises outputting a signal corresponding to the analyte's concentration (column 16, lines 31-38); analyzing the concentration signal (column 18, lines 42-50); and outputting the analysis result (column 18, lines 47-48).

Regarding Claim 29, Conn discloses a method comprising forming analyte transmission paths in skin (column 8 line 60 to column 9 line 7); placing a through-current electrode part and a first electrode part on skin in the location where the analyte transmission paths have already been formed, since the transmission enhancing techniques, such as pricking, would take place prior to application of electrodes (column 15, lines 24-34; column 18, lines 4-6); applying electrical energy to the electrode parts (column 15, lines 27-34); and extracting analyte at the first electrode part (column 15, lines 34-36).

Regarding claim 36, Conn further discloses that the first extraction electrode part may have a contact area with the skin of less than about 50 mm^2 (column 18, lines 4-6).

4. Claims 19, 20, and 22 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim.

Regarding Claim 19, the examiner notes that the device of Kim is capable of being used as claimed because the device comprises a first electrode (element 40) with an area of less than 50 mm^2 (column 16, lines 65-67); an electrode for extracting an analyte (element 42); a through-current electrode (element 44); and a power supply used to supply power to all the electrodes (column 18, lines 11-20).

Regarding Claim 20, Kim further discloses that the contact area may be about 25 mm² (column 16, lines 65-67), because 0.3 cm² (30 mm²) is about 25 mm².

Regarding Claim 22, Kim further discloses a second path-forming electrode (element 41) with an area of less than 50 mm² (column 16, lines 65-67); a second electrode for extracting an analyte (element 43); a second through-current electrode (element 45); and a power supply used to supply power to all the electrodes (column 18, lines 11-20).

5. Claims 3, 8-11, 26-27, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn in view of Avrahami (US Patent Application Publication 2004/0230227).

Regarding Claim 3, Conn discloses all the elements of the current application, as described above, except for the current flowing from the power supply part, through the through-current electrode into the skin, then into the first electrode part and finally back to the power supply part.

Avrahami discloses a transdermal analyte extraction device comprising a through-current electrode and a first electrode (elements 120 or 124) and a power supply (elements 50 and 98), wherein the current flows from the power supply part, through the through-current electrode into the skin, then into the first electrode part and finally back to the power supply part (Figure 4), in order to more efficiently extract analytes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn with the specific current flows of Avrahami, in order to more efficiently extract analytes.

Regarding Claim 8, Conn discloses all the elements of the current application, as described above, except for the device comprising a second electrode part having the same contact area as the first electrode part, and the power supply part of the device comprising power supplies for both the first and second electrode parts.

Avrahami discloses a transdermal analyte extraction device comprising a plurality of identical electrode parts (Figure 2), each with a power supply (Figure 4), in order to more thoroughly sample analytes from a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn, with additional electrodes, each with a power supply, as taught by Avrahami, in order to more thoroughly sample analytes from a patient.

Regarding Claim 9, the plurality of duplicate electrode parts comprising the device of Conn in view of Avrahami may have a contact area of about 25 mm^2 , as taught by Conn (column 18, lines 4-6), because $.3 \text{ cm}^2$ (30 mm^2) is about 25 mm^2 .

Regarding Claim 10, the plurality of duplicate electrode parts comprising the device of Conn in view of Avrahami may each comprise an electrode (element 14) connected to the power part and an analyte collection material (elements 4 and 8) that contacts the electrode (column 15, lines 29-36).

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Regarding Claim 11, Conn in view of Avrahami discloses all the elements of the current invention except for the first and second electrode parts being integrated.

Avrahami further discloses that the plurality of electrode parts are integrated within a single housing (Figure 2), in order to facilitate application upon a patient's skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn in view of Avrahami, and integrated the electrode parts, as taught by Avrahami, in order to facilitate application upon a patient's skin.

Regarding Claim 26, Conn discloses all the elements of the current invention, as described above, except for the method comprising placing a second electrode part having the same contact area as the first electrode part on the skin, supplying it with electrical energy, and extracting analyte at the duplicate electrode.

Avrahami discloses a method of transdermal analyte extraction comprising a placing a plurality of identical electrode parts (Figure 2) on a patient's skin, each with a power supply (Figure 4), and using them to transdermally extract analyte, in order to more thoroughly sample analytes from a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Conn, with the steps of adding, powering, and sampling from additional electrodes, as taught by Avrahami, in order to more thoroughly sample analytes from a patient.

Regarding Claim 27, Conn in view of Avrahami discloses all the elements of the current invention, as disclosed above, except for the first and second electrode parts being placed on the skin substantially simultaneously.

Avrahami further discloses that the plurality of electrode parts are disposed within a single housing (Figure 2) and are therefore placed on the skin substantially simultaneously, in order to more efficiently apply the sampling apparatus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Conn in view of Avrahami, and applied the electrode parts simultaneously, as taught by Avrahami, in order to more efficiently apply the sampling apparatus.

Regarding Claim 32, Conn discloses all the elements of the current invention, as described above, except for the method comprising placing a second extraction electrode part on the skin, supplying it with energy, and using it to extract analyte.

Avrahami discloses a method of transdermal analyte extraction comprising a placing a plurality of identical electrode parts (Figure 2) on a patient's skin, each with a power supply (Figure 4), and using them to transdermally extract analyte, in order to more thoroughly sample analytes from a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Conn, with the steps of adding, powering, and sampling from additional electrodes, as taught by Avrahami, in order to more thoroughly sample analytes from a patient.

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6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conn in view of Glikfeld (US Patent 5279543).

Conn discloses all the elements of the current invention, as described above, except for the power supply part outputting a voltage of less than about 10 V.

Glikfeld teaches a device comprising a pair of electrodes for extraction of an analyte, where the power supplied by a power supply part is less than about 10 V (column 7, lines 63-64), in order to prevent harm to the patient from excess voltage.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn and used the power supply part to output a voltage of less than about 10 V, as taught by Glikfeld, in order to prevent harm to the patient from excess voltage.

7. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn in view of Ackerman (US Patent Application Publication 2003/0208114).

Regarding Claim 12, Conn discloses all the elements of the current invention, as described above, except for the power supply part supplying constant current.

Ackerman discloses a device for transdermal analyte extraction comprising a part to supply direct (constant) current, in order to facilitate analyte extraction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn, with a constant current power supply, as taught by Ackerman, in order to facilitate analyte extraction.

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Regarding Claim 16, Conn discloses all the elements of the current invention, as described above, except for the extraction acceleration part comprising ultrasonic irradiation.

Ackerman discloses a device for transdermal analyte extraction comprising a part to apply ultrasonic irradiation, in order to facilitate analyte extraction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Conn with the part for applying ultrasonic irradiation, as taught by Ackerman, in order to facilitate analyte extraction.

Allowable Subject Matter

8. Claims 21, 23, 30-31, 33 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to anticipate or make obvious the structure of claim 38, including, *inter-alia*, a transdermal analyte extraction device with an electrode with a skin-contacting area of about 0.01 to 25 mm².

The allowability of these claims has been discussed in the previous office action.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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